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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,242	02/09/2009	Travis Marsot	38187-2836	5504

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Goodwin Procter LLP
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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,242	MARSOT ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-9,11-13 and 21-27* is/are rejected.

7)☒ Claim(s) *10 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 26 and 27 have been renumbered 27 and 28.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the texture structures as claimed in Claim 21 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2-5, 21, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2 and 5 have been amended to incorporate subject matter directed towards the texture surface being designed to account for surface tension, bulk properties and surface flow of the cartridge. The current specification does not disclose the texturing is designed to account for surface tension, bulk properties and surface flow *of the cartridge*. The current specification only discloses designing the texturing to account for surface tension, bulk properties and surface flow, and makes no mention of the properties of the cartridge. Furthermore, based on the current specification, the Examiner is assuming

the claim language is directed towards designing the texturing based on the blood properties (surface tension, bulk properties (density), and surface flow). Regarding Claim 24, the current specification fails to disclose the mesh structure is pliable enough to allow for the relaxation *of the tissue*. The current specification only discloses the mesh structure being pliable enough to allow for relaxation, and makes no mention of providing for relaxation of the tissue.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 2-5, 11-13, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Boecker et al (2004/0098009 A1).

Boecker et al disclose a means for body fluid sampling and analysis and further disclose a single cartridge; a penetrating member coupled to the single cartridge; an analyte detecting member; providing a single cartridge configured to slidably hold a plurality of penetrating members and to have a plurality of analyte detecting members; using surface texturing to direct fluid into a desired area on the cartridge (wicking elements, etc); the texturing is designed to account for surface tension, bulk properties

and surface flow; the texturing is formed chemically (printing on the surface to produce an analyte detection surface requires a chemical reaction); the texturing guides the fluid to one of the analyte detecting members; a plurality of penetrating members coupled to the single cartridge and operatively couplable to a penetrating member driver, the penetrating members movable to extend radially outward from the cartridge to penetrate tissue; a support structure; a sensory material on a first side of the support structure; a conductor material coupled to the sensory material; a commutator positioned to engage the conductor material to obtain analyte measurements; a radial cartridge, the support structure coupled to the radial cartridge; and a plurality of electrodes, each having the sensory material; the texture structure is a cross-hatch or criss-cross in shape (wicking elements are often paper or fabric in nature, wherein the manufacture of such elements creates a cross-hatch or criss-cross texture); and the textured surface improves user feedback and sensation of contact to let the user know whether the user is in target (texturing inherently improves feedback and sensation). See Figures 1 and 2; Paragraphs 0006, 0007, 0142, 0143, 0176 and 0184.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 6-9 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boecker et al (2004/0092995 A1) in view of Cunningham et al (6,093,156).

Boecker et al disclose a fluid sampling and analyte sensing means and further disclose a single cartridge; a plurality of penetrating members coupled to the single cartridge and operatively couplable to the penetrating member driver; the penetrating members movable to extend radially outward from the cartridge to penetrate tissue; a plurality of analyte detecting members coupled to the single cartridge, wherein at least one of the analyte detecting members positioned on the cartridge to receive body fluid from a wound in tissue created by the penetrating member when the cartridge in an operative position; a mesh structure to draw fluid generated by the tissue towards one of the analyte detecting members; a ring around the cartridge wherein the analyte detecting members are mounted on the ring, along with the mesh; a ring around the cartridge wherein the analyte detecting members are coupled to the cartridge through the ring; and a plurality of electrodes coupled to the analyte detecting member. See Figures 1, 2 and 73-78; Paragraphs 0173, 0179, 0184 and 0230.

Boecker et al however fail to disclose a mesh structure pushed and pierced by the penetrating member against the tissue in order to draw fluid to the analyte detecting member; the mesh is made of capillary fibers; the mesh structure is pliable enough to allow relaxation; and the mesh structure distributes impact of the penetrating member on the tissue.

Cunningham et al disclose a lancing apparatus and further disclose a mesh structure pushed and pierced by the penetrating member against the tissue in order to

draw fluid to the analyte detecting member; the mesh is made of capillary fibers (the mesh is comprised of very small fibers to wick blood from the wound; therefore the fibers are considered to be “capillary fibers”); the mesh structure is pliable enough to allow relaxation (the mesh structure is not a rigid structure); and the mesh structure distributes impact of the penetrating member on the tissue (a mesh structure would inherently distribute the force of the penetrating needle). See Column 24, lines 63-64.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mesh placement, and the mesh has specific physical properties, as per the teachings of Cunningham et al, since it would provide a more efficient means of lancing the skin to obtain a blood sample for analysis. It also would have been obvious to one of ordinary skill in the art that a mesh stretched over an opening would reduce the amount of blood that spontaneously arises to the surface of the skin because the mesh would evenly distribute the contact force of the device over the opening on the skin, such that the pressure would prevent the blood from spontaneously arising after the skin has been penetrated.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boecker et al (2004/0092995 A1) and Cunningham et al (6,093,156) as applied to claim 6 above, and further in view of Shen et al (2004/0231983 A1).

Boecker et al and Cunningham et al, as discussed above, disclose a lancing apparatus using a mesh to cover the opening, such that the mesh is pushed and pierced by the lancet, but fail to disclose the mesh is a hydrophilic mesh that allows fluid to be absorbed.

Shen et al disclose an electrochemical sensor and further disclose the mesh is a hydrophilic mesh. See Paragraphs 0034 and 0044.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Boecker et al and Cunningham et al to utilize a hydrophilic mesh, as per the teachings of Shen et al, since a hydrophilic mesh would allow the blood sample to efficiently permeate the mesh to advance to the electrochemical sensors to detect the presence of a specific analyte.

Allowable Subject Matter

10. Claims 10 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments filed April 16, 2010 have been fully considered but they are not persuasive.

The Applicant argues the prior art of Boecker et al ('995) and Boecker et al ('009) both fail to disclose surface textures designed to account for surface tension, bulk properties and surface flow of the cartridge. As stated above, the current specification does not support surface textures designed to account for surface tension, bulk properties and surface flow *of the cartridge*. {emphasis added} The current specification does disclose designing textures to account surface tension, bulk properties and

surface flow. However, one of ordinary skill in the art could interpret the current specification as disclosing the design of textures to account for properties of the blood, and not the cartridge, such that the blood would be wicked away form the skin to the analyte detection area.

The Applicant also argues the prior art of Boecker et al ('995) and Boecker et al ('009) both fail to disclose raised textures instead of carved textures on the cartridge. The Examiner would like to respectfully point out the language of Claim 21 discloses raised textures as one of the alternatives of the texture structures and does not solely claim the raised texture structure.

The Applicant also argues the prior art of Boecker et al ('995) do not disclose a mesh structure to allow for relaxation of the tissue. As stated above, the current specification fails to disclose the mesh structure is designed to allow for the relaxation of tissue. At best, the current specification only discloses the mesh structure is capable of relaxation. The "relaxation" as disclosed in the current specification could be interpreted as the mesh having some sort of elastic property.

The Applicant also argues neither Boecker et al ('995) nor Boecker et al ('009) disclose a commutator positioned to engage the conductor material coupled to the sensory material to obtain analyte measurements. Boecker et al ('009) disclose the use of electrochemical analyte detecting members placed in a ring-shaped orientation, as seen in Figure 73 and Paragraph 0184. As seen in Figure 73, the lancet wheel includes a separate portion comprising individual analyte detection elements associated with each of the lancets on the lancet wheel. One of ordinary skill in the art, based on Figure

73 and Paragraph 0184, would be able to determine each individual analyte detection element would inherently require a commutator to electrically link the sensory material (and the conductor material coupled thereto) to the analytical device to ultimately display the detected amount of analyte in the fluid sample. Otherwise, each individual analyte detection element would be separately and simultaneously coupled to the analytical device, for instance via wires, and would therefore prevent the rotation of both the lancet/analyte detection element.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736